GENTLE LAXATIVE- bisacodyl tablet, coated Meijer Distribution Inc

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Meijer 44-327

Active ingredient (in each tablet)

Bisacodyl USP, 5 mg

Purpose

Stimulant laxative

Uses

- for relief of occasional constipation and irregularity
- this product generally produces bowel movement in 6 to 12 hours

Warnings

Do not use

if you cannot swallow without chewing.

Ask a doctor before use if you have

- stomach pain, nausea or vomiting
- a sudden change in bowel habits that lasts more than 2 weeks

When using this product

- do not chew or crush tablet(s)
- do not use within 1 hour after taking an antacid or milk
- you may have stomach discomfort, faintness and cramps

Stop use and ask a doctor if

- you have rectal bleeding or fail to have a bowel movement after use of a laxative. These could be signs of a serious condition.
- you need to use a laxative for more than 1 week

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

take with a glass of water

| adults and children 12 | take 1 to 3 tablets in a |
|------------------------|---------------------------|
| years and over | single daily dose |
| children 6 to under 12 | take 1 tablet in a single |
| years | daily dose |
| children under 6 years | ask a doctor |

Other information

- TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- avoid excessive humidity
- see end flap for expiration date and lot number

Inactive ingredients

acacia, ammonium hydroxide, calcium carbonate, carnauba wax, colloidal anhydrous silica, corn starch, D&C yellow #10 aluminum lake, FD&C yellow #6 aluminum lake, hypromellose, iron oxide black, lactose anhydrous, magnesium stearate, methylparaben, polydextrose, polyethylene glycol, polyvinyl acetate phthalate, povidone, propylene glycol, propylparaben, shellac glaze, simethicone, sodium alginate, sodium benzoate, sodium bicarbonate, stearic acid, sucrose, talc, titanium dioxide, triacetin, triethyl citrate

Questions or comments?

1-800-426-9391

Principal Display Panel

meijer®

NDC 41250-339-56

Compare to Dulcolax® Laxative Tablets active ingredient*

gentle laxative Bisacodyl USP | 5 mg Stimulant Laxative

For Gentle, Dependable, Constipation Relief

25 Tablets (Enteric Coated)

Actual Size

TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING

*This product is not manufactured or distributed by Sanofi-Aventis Deutschland GMBH, owner of the registered trademark Dulcolax® Laxative Tablets. 50844 REV0119A32756

DIST. BY MEIJER
DISTRIBUTION, INC.
GRAND RAPIDS, MI 49544
www.meijer.com

Meijer 44-327

GENTLE LAXATIVE

bisacodyl tablet, coated

| Product | Information |
|---------|-------------|
|---------|-------------|

Product Type HUMAN OTC DRUG Item Code (Source) NDC:41250-339

Route of Administration

ORAL

| Active Ingredient/Active Moiety | | | | |
|--|-------------------|----------|--|--|
| Ingredient Name | Basis of Strength | Strength | | |
| BISACODYL (UNII: 10X0709Y6I) (DEACETYLBISACODYL - UNII:R09078E41Y) | BISACODYL | 5 ma | | |

| Inactive Ingredients | |
|---|----------|
| Ingredient Name | Strength |
| ACACIA (UNII: 5C5403N26O) | |
| AMMONIA (UNII: 5138Q19F1X) | |
| CALCIUM CARBONATE (UNII: H0G9379FGK) | |
| CARNAUBA WAX (UNII: R12CBM0EIZ) | |
| STARCH, CORN (UNII: O8232NY3SJ) | |
| D&C YELLOW NO. 10 ALUMINUM LAKE (UNII: CQ3XH3DET6) | |
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8) | |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) | |
| FERROSOFERRIC OXIDE (UNII: XM0M87F357) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| METHYLPARABEN (UNII: A2I8C7HI9T) | |
| POLYDEXTROSE (UNII: VH2XOU12IE) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| POVIDONE, UNSPECIFIED (UNII: FZ989GH94E) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| PROPYLPARABEN (UNII: Z8IX2SC10H) | |
| SHELLAC (UNII: 46N107B710) | |
| DIMETHICONE (UNII: 92RU3N3Y1O) | |
| SODIUM ALGINATE (UNII: C269C4G2ZQ) | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| SUCROSE (UNII: C151H8M554) | |
| TALC (UNII: 7SEV7J4R1U) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| TRIACETIN (UNII: XHX3C3X673) | |
| TRIETHYL CITRATE (UNII: 8Z96QXD6UM) | |
| ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| Polyvinyl Acetate Phthalate (UNII: 58QVG85GW3) | |
| WATER (UNII: 059QF0KO0R) | |

| Product Characteristics | | | | |
|-------------------------|--------|--------------|----------|--|
| Color | orange | Score | no score | |
| Shape | ROUND | Size | 6mm | |
| Flavor | | Imprint Code | 5 | |
| Contains | | | | |

| F | ackaging | | | |
|---|------------------|---|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:41250-339-56 | 1 in 1 CARTON | 06/29/2020 | |
| 1 | | 25 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |

| Marketing Information | | | | | |
|-------------------------|--|----------------------|--------------------|--|--|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | | |
| OTC monograph not final | part334 | 06/29/2020 | | | |
| | | | | | |

Labeler - Meijer Distribution Inc (006959555)

| Establishment | | | | |
|-------------------------|---------|-----------|----------------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| LNK International, Inc. | | 832867894 | manufacture(41250-339) | |

| Establishment | | | |
|-------------------------|---------|-----------|---------------------|
| Name | Address | ID/FEI | Business Operations |
| LNK International, Inc. | | 832867837 | pack(41250-339) |

| Establishment | | | | |
|-------------------------|---------|-----------|---------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| LNK International, Inc. | | 967626305 | pack(41250-339) | |

| Establishment | | | | |
|-------------------------|---------|-----------|----------------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| LNK International, Inc. | | 038154464 | pack(41250-339) | |

| Establishment | | | | |
|-------------------------|---------|-----------|----------------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| LNK International, Inc. | | 868734088 | pack(41250-339) | |

Revised: 8/2021 Meijer Distribution Inc